

October 26, 1999



The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statement:

(1) Vasculin contains bovine heart PMG<sup>TM</sup> extract, in addition to vitamin B and E complexes that support the healthy functioning of the heart muscle.

This statement is made for a dietary supplement containing a proprietary blend of bovine heart PMG<sup>TM</sup> extract, nutritional yeast, veal bone PMG<sup>TM</sup> extract, rice (bran) extract, bovine liver, oat flour, porcine duodenum, inositol, dried pea (vine) juice, bovine adrenal Cytosol<sup>TM</sup> extract, dried beet (root) juice, ribonucleic acid, defatted wheat (germ), choline bitartrate, dried alfalfa juice, dried buckwheat (leaf) juice, buckwheat (seed), mushroom, alfalfa flour, bovine spleen, ovine spleen, soy bean lecithin. Other ingredients include calcium lactate, calcium citrate, honey, niacinamide, potassium para-aminobenzoate, ascorbic acid, calcium stearate, gelatin, mixed tocopherols, pyridoxal 5-phosphate, cocarboxylase, cellulose, and cyanocobalamin. And the name of the product is Vasculin®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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